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PKGI-76-G EFFECTIVE 12-2018



# **ACUMED® STERILIZATION IN AESCULAP® STERILIZATION CONTAINERS**

# FOR THE PERSONAL ATTENTION OF THE OPERATING SURGEON

**DESCRIPTION:** The Acumed system configurations listed below have been validated for sterilization in the specified Aesculap sterilization containers.

**INFORMATION FOR USE:** Acumed Instructions for Use for implant and instrument systems can be found by part number at http://www.acumed.net/ifu. These instructions include product descriptions, information for use, indications, contraindications, warnings, precautions, adverse effects, cleaning instructions, and storage instructions for the personal attention of the operating surgeon.

Additional Aesculap Instructions for Use are provided by Aesculap. These instructions can be found by Aesculap Item Number at http://www.aesculapusa.com/ and must be reviewed prior to use of Aesculap sterile containers. Item Numbers can be found in the table below

#### **CLEANING:**

Cleaning of Aesculap sterilization containers should be completed in adherence to the Instructions for Use provided by Aesculap.

Cleaning of the Acumed products should be completed in adherence to the part or system Instructions for Use provided by Acumed by product part number.

## STERILITY

These products are non-sterile, and must be sterilized by the hospital prior to use. Nonsterile devices have been validated using the sterilization parameters listed below, in fully-loaded trays with all parts placed appropriately. Sterilization must be completed in adherence to the additional Instructions for Use provided by Aesculap.

### Sterilization Methods

- Consult your equipment manufacturer's written instructions for specific sterilizer and load configuration instructions.
- Follow current AORN "Recommended Practices for Sterilization in Perioperative Practice Settings" and ANSI/AAMI ST79: 2010 Comprehensive guide to steam sterilization and sterility assurance in health care facilities.
- Flash sterilization is not recommended, but if used, should only be performed according to requirements of ANSI/AAMI ST79: 2010 – Comprehensive guide to steam sterilization and sterility assurance in health care facilities.





| Validated Configurations and Parameters: |                              |  |  | Pre-Viocum Autoclave        |                          |                   |            |
|--|------------------------------|--|--|-----------------------------|--------------------------|-------------------|------------|
| Acumed System<br>Contained:              | Aesculap<br>Item<br>Numbers: | Corresponding<br>Acumed Part<br>Numbers: | Caddies/Trays Numbers Contained:   | Pre-Conditioning<br>Pulses: | Exposure<br>Temperature: | Exposure<br>Time: | Dry Time:  |
| Acu-Loc 2                                | JN442<br>JK489               | 80-2096<br>80-2098                       | 80-0346, 80-0347, 80-0748, 80-0751, 80-0752, 80-0754, 80-0787, 80-0790, 80-0822, 80-0825, 80-0826, 80-1009, 80-1010, 80-1500 and 80-1502 | SO.                         | <u>٠</u>                 | 4 minutes         | 30 minutes |
| Acutrak 2                                | JN441<br>JK489               | 80-2095<br>80-2098                       | AT2-004, AT2-005, AT2-006, and AT2-007   | 4                           |                          | 10 minutes        | 40 minutes |
| Acutrak Fusion                           | JN187<br>JK174               | 80-2109<br>80-2111                       | ATF-060 (without lid) and ATF-061  | 3                           |                          | 4 minutes         | 30 minutes |
| Anatomic Radial Head<br>System           | JN444<br>JK489               | 80-2097<br>80-2098                       | 80-0364, TR-0001 (without base and lid),<br>and AT2-006  | $\sqrt{3}$                  |                          | 25 minutes        | 70 minutes |
| Anatomic Radial Head                     | JN440<br>JK489               | 80-2094<br>80-2098                       | 80-0365, AT2-006, 80-2942  | 4                           | 270° F<br>(132° C)       | 4 minutes         | 30 minutes |
| Solutions                                | JN442<br>JK489               | 80-2096<br>80-2098                       | 80-2002, 80-2003, 80-2942  | 4                           |                          | 4 minutes         | 30 minutes |
| Ankle Plating System 3                   | JN441<br>JK489               | 80-2095<br>80-2098                       | 80-2340, 80-2341,<br>80-2342, 80-2343  | 3                           |                          | 4 minutes         | 30 minutes |
| Arc Wrist Tower Tray 1                   | JN440<br>JK489<br>JF222R     | 80-2094<br>80-2098<br>80-2116            | None (only parts)  | 3                           |                          | 4 minutes         | 60 minutes |
| Arc Wrist Tower Tray 2                   | JN442<br>JK489               | 80-2096<br>80-2098                       | 10100003 (without lid)   | 3                           |                          | 4 minutes         | 60 minutes |





| Validated Configurations and Parameters: (continued) |                                   |  |  | Pra-vac.um Autoclave        |                          |                   |            |
|--|-----------------------------------|--|--|-----------------------------|--------------------------|-------------------|------------|
| Acumed System<br>Contained:                          | Aesculap<br>Item<br>Numbers:      | Corresponding<br>Acumed Part<br>Numbers: | Caddies/Trays Numbers Contained:   | Pre-Conditioning<br>Pulses: | Exposure<br>Yemperature: | Exposure<br>Time: | Dry Time:  |
| Bone Graft   | JN188<br>JK174<br>JF159R<br>MD894 | 80-2110<br>80-2111<br>80-2115<br>80-2119 | None (only parts)  |                             | 0.                       | 4 minutes         | 30 minutes |
| 6.5/7.3mm Cannulated<br>Screw System                 | JN445<br>JK490                    | N/A<br>80-2712                           | 80-1823 and 80-1824  | 4                           | )                        | 4 minutes         | 30 minutes |
| 4.0mm Cannulated<br>Screw System                     | JN341<br>JK389                    | 80-2108<br>80-2105                       | 80-3683, 80-3684, 80-3685, 80-3686, 80-3687,<br>80-3688, 80-3695   | 0                           |                          | 4 minutes         | 30 minutes |
| Clavicle System with<br>Dual-Trak Platter            | JN442<br>JK489                    | 80-2096<br>80-2098                       | 80-0308, 80-0344, 80-0345, 80-0346, 80-0525, 80-0785, 80-0843, 80-0856, 80-1066 and 80-1067                            | 3                           |                          | 25 minutes        | 70 minutes |
| Clavicle System with<br>Scapula Platter              | JN442<br>JK489                    | 80-2096<br>80-2098                       | 80-0136, 80-0308, 80-0344, 80-0345, 80-0346, 80-0350, 80-0351, 80-0352, 80-0525, 80-0843, 80-0856, 80-1066 and 30-1067 | 3                           | 270° F<br>(132° C)       | 25 minutes        | 70 minutes |
| Elbow Plating System                                 | JN442<br>JK489                    | 80-2096<br>80-2098                       | 80-0629, 80-0678, 80-0677, 80-0676, 80-0675  | 4                           |                          | 4 minutes         | 30 minutes |
| Fibula Rod   | JN442<br>JK489                    | 80-2096<br>80-2098                       | 80-0117, 80-0116   | 4                           |                          | 10 minutes        | 30 minutes |
| Forearm Rod  | JN442<br>JK489                    | 80-2096<br>80-2098                       | ROD-1001 (without base and lid)  | 3                           |                          | 4 minutes         | 30 minutes |
| Forearm Solutions                                    | JN442<br>JK489                    | 80-2096<br>80-2098                       | 80-1915, 80-1916, 80-1917, 80-1918, 80-1922  | 4                           |                          | 4 minutes         | 30 minutes |





| Validated Configurations and Parameters: (continued)                                   |                                   |  |   | Pre-V to um Autoclave   |                          |                   |            |
|--|-----------------------------------|--|---|-------------------------|--------------------------|-------------------|------------|
| Acumed System Contained:   | Aesculap<br>Item<br>Numbers:      | Corresponding<br>Acumed Part<br>Numbers: | Caddies/Trays Numbers Contained:  | Pre-Conditionin Pulses: | Exposure<br>Temperature: | Exposure<br>Time: | Dry Time:  |
| Hand Fracture  | JN440<br>JK489<br>JF222R          | 80-2094<br>80-2098<br>80-2116            | 80-2391, 80-2392, 80 1981   | So.                     | <b>∼</b> ·               | 4 minutes         | 30 minutes |
|  | JN441<br>JK489                    | 80-2095<br>80-2098                       | 80-1817, 80-1815, 80-0347   | 11                      | <b>)</b> '               |                   |            |
| Large Acutrak 2  | JN441<br>JK489                    | 80-2095<br>80-2098                       | 80-0870, 80-0871, 80-0876, 80-0877, 80-0878,<br>80-0879, 80-0880, 80-0881, 80-0882, 80-0883 | 4                       |                          | 4 minutes         | 30 minutes |
| Lower Extremity<br>Modular System with<br>Ankle and Calcaneal<br>Platters              | JN444<br>JK489                    | 80-2097<br>80-2098                       | 80-0427 80-0428, 80-0434, 80-0744 and 80-1501   | 4                       | 270° F<br>(132° C)       | 4 minutes         | 30 minutes |
| Lower Extremity<br>Modular System with<br>Locking Forefoot/<br>Midfoot Plating Platter | JN444<br>JK489                    | 80-2097<br>80-2098                       | 80-0427, 80-0428, 80-0590 and 80-1501   | 3                       | (132-0)                  | 4 minutes         | 30 minutes |
| Midshaft Forearm<br>Plate Platter  | JN740<br>JK789<br>JF252R<br>MD897 | 80-2099<br>80-2103<br>80-2117<br>80-2121 | 80-0183, 80-1530  | 3                       |                          | 4 minutes         | 30 minutes |
| Modular Hand   | JN341<br>JK389                    | 80-2105<br>80-2108                       | PL-WFL4, PL-WFL5, PL-WFL6, PL-WF02, PL-WF03, PL-WF04, PL-WF05, PL-WF06                      | 3                       |                          | 25 minutes        | 60 minutes |
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| Validated Configurations and Parameters: (continued) |                              |  |                                      | Pre-Nocum Autoclave     |                          |                   |            |
|--|------------------------------|--|--------------------------------------|-------------------------|--------------------------|-------------------|------------|
| Acumed System<br>Contained:                          | Aesculap<br>Item<br>Numbers: | Corresponding<br>Acumed Part<br>Numbers: | Caddies/Trays Numbers Contained:     | Pre-Conditionin Pulses: | Exposure<br>Temperature: | Exposure<br>Time: | Dry Time:  |
|  | JN444<br>JK489               | 80-2097<br>80-2098                       | 80-1929, 80-1930                     | SO.                     | <b>∼</b> ·               |                   |            |
| Polarus 3  | JN444<br>JK489               | 80-2097<br>80-2098                       | 80-1934, 80-1935                     | 4                       | <b>)</b>                 | 4 minutes         | 30 minutes |
|  | JN444<br>JK489               | 80-2097<br>80-2098                       | 80-1936, 80-2352                     | 16/                     | 270° F<br>(132° C)       |                   |            |
| Polarus Humeral Rod                                  | JN821<br>JE601<br>JE167R     | 80-2113<br>80-2114<br>80-2118            | MS-9000 (without base and lid)       | 3                       |                          | 4 minutes         | 30 minutes |
| Small Fragment Base<br>Set w/VA screws               | JN444<br>JK489               | 80-2097<br>80-2098                       | 80-2383, 80-2384<br>80-2628, 80-2629 | 4                       |                          | 4 minutes         | 30 minutes |
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| PKGI-76-G Effective 12-201                           |                              |  |                                      |                         |                          | — <b>-</b> + a∈   | cumed      |



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**FURTHER INFORMATION:** To request further material, please see the contact information listed on this document.

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| S                      | YMBOL LECEND   |  |  |  |
|------------------------|--|--|--|--|
| $\bigcap_{\mathbf{i}}$ | Consult instructions for use                           |  |  |  |
| $\triangle$            | Caution  |  |  |  |
| STERILE EO             | Sterilized using ethylene oxide                        |  |  |  |
| STERILE R              | Sterilized using irradiation                           |  |  |  |
| Ξ                      | Use by date  |  |  |  |
| REF                    | Catalogue number                                       |  |  |  |
|                        | Batch code   |  |  |  |
| EQ REP                 | Authorized representative in the<br>European Community |  |  |  |
|                        | Manufacturer   |  |  |  |
|                        | Date of manufacture                                    |  |  |  |
|                        | Do not resterilize                                     |  |  |  |
| 2                      | Do not re-use  |  |  |  |
| X                      | Upper limit of temperature                             |  |  |  |
|                        |  |  |  |  |

Cautions: U.S. Federal Law restricts this product sale by or on the order of a physician. For Professional Use Only.

